REMARKS

Claims 27-34, 38-44 and 48-56 are pending following entry of the amendments presented above. In order to expedite prosecution, and without prejudice, Claims 27, 38, 39, 40 and 49 are amended herein, and Claims 35-37 and 45-47 are cancelled herein. In addition, new Claims 50-56 are added herein.

Claims 27-49 stand rejected under 35 U.S.C.§112, first paragraph, as allegedly non-enabled.

Claims 27-38 and 46 stand rejected under 35 U.S.C.§112, second paragraph, for allegedly being indefinite.

Claims 27-49 stand rejected under 35 U.S.C.§102(b) as allegedly being anticipated by, or in the alternative under 35 U.S.C.§103(a) for obviousness over, U.S. Patent No. 6,071,439 to Bawa et al. ("Bawa").

Claims 27-49 stand rejected under 35 U.S.C.§103(a) as allegedly unpatentable for obviousness, over "Active growth factor delivery from poly(D,L-lactide-coglycolide) foams prepared in supercritical CO_2" by David D. Hile *et al.* ("Hile") in view of U.S. Patent No. 5,916,585 to Cook et al. ("Cook").

Applicants respectfully traverse the outstanding rejections for at least the reasons set forth below.

Interview Summary

Applicants wish to express their appreciation to the Examiner for the time and courtesy extended toward the Applicants' representatives, Karen Magri and Lori Herman, during the interview at the United States Patent and Trademark Office on November 16, 2006. During the interview, the art rejections and possible claim amendments were discussed.

The Claim Amendments are Supported by the Specification as Originally Filed

For the Examiner's convenience, a clean copy of the amended claim set is attached hereto.

Claim 27 has been amended to specifically recite various polymers and co-polymers. This claim amendment is supported by the application as filed at page 8, line 34 through page 9, line 29.

Claim 27 has further been amended to specifically recite a "stent." This amendment is supported by the application as filed at page 7, lines 21 of the specification. Claims 38-40 and 49 have also been amended to recite "stent."

Claim 39 has been amended to recite specific copolymers. This amendment is supported by the application as filed at page 9, lines 18-22.

Claim 40 has been amended to recite specific lactic acid polymers and copolymers. This claim language is supported by the application as filed at page 9, lines 11-12 and 18.

New Claim 50 is similar to Claim 27, except that Claim 50 specifically recites "poly(glycolic acid), poly(D-lactic-co-glycolic acid), poly(L-lactic-co-glycolic acid), poly (D,L-lactic-co-glycolic acid), and a copolymer of poly(glycolic acid), poly(D-lactic-co-glycolic acid), poly(L-lactic-co-glycolic acid), or poly (D,L-lactic-co-glycolic acid)." This claim language is supported by the application as filed at page 9, lines 12-14 and 18.

New dependent Claims 51-56 are similar to Claims 41-44 and 48-49, except that new Claims 51-56 depend from Claim 50.

In view of the foregoing, Applicants submit that the claim amendments and new claims are supported by the specification as filed, and respectfully request entry thereof.

The Claims are Enabled

Claims 27-49 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly non-enabled for reciting "masking." Applicants respectfully disagree with this rejection. Nonetheless, the "masking" step has been removed from the claims, thereby obviating this rejection.

The Communication further objects that the specification allegedly "identifies the same polymers as erodible and non-erodible." As discussed at the November 16, 2006 interview, it is well-known by those skilled in the art that certain classes of polymers include erodible and non-erodible polymers (*i.e.*, some species in the genus are erodible and some are non-erodible). Nonetheless, this rejection has been obviated as Claims 27-34, 38-44 and 48-49 now recite specific polymers and copolymers.

Accordingly, it is respectfully requested that the outstanding rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

The Claims are Sufficiently Clear

Claims 27-38 and 46 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for reciting "masking." As discussed above, the masking step has been omitted from the claims, thereby obviating this rejection. Accordingly, it is respectfully requested that the outstanding rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

§102(b) Rejection over Bawa is Overcome

Claims 27-49 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Bawa or, in the alternative, as obvious in view of Bawa. Applicants respectfully disagree with this rejection. Nonetheless, Claims 35-37 and 45-47 are herein canceled without prejudice, thus mooting the rejection as it applies to these claims. Regarding pending Claims 27-34, 38-44 and 48-49, this rejection is respectfully traversed below.

As an initial point, Applicants wish to clarify that Bawa does not disclose methods of treating intraluminal prostheses or, more specifically, stents. The Communication cites column 6, lines 14-28 of Bawa for disclosing a "vessel substitute." As discussed at the November 16, 2006 in-person interview, stents are not vessel substitutes, and there is no disclosure of stents in Bawa.

Moreover, Bawa fails to disclose or suggest any of the polymers recited in pending Claims 27-34, 38-44 and 48-49.

Thus, as Bawa does not disclose or suggest the claimed methods of (i) treating stents or (ii) any of the recited polymers, the present invention is both novel and nonobvious over this reference.

More specifically, the Bawa reference is concerned with methods of manufacturing contact lenses. Bawa's focus is on soft hydrogel contact lenses; in fact, all of the examples provided in the patent are directed toward siloxane hydrogel lenses, which are crosslinked elastomers. As explained in the Declaration Under 37 C.F.R. §1.132 of Joseph M. DeSimone, Ph.D. (*hereinafter*, "the DeSimone Declaration") at paragraph 6, a crosslinked elastomer (such as the polysiloxane hydrogels of Bawa) cannot be melted because the crosslinked chains of the polymer are "locked" into a three-dimensional network. Thus, little to no deformation will occur to the macroscopic polymer structure upon heating and/or application of densified carbon dioxide. In addition, due to the "rubbery" nature of elastomers, once the polymer is cooled or brought to ambient pressure, any deformation to the polymer structure will be be diminished as the polymer returns to its original form. *See* DeSimone Declaration at para. 8.

In contrast, the specific polymers recited in Claims 27-34, 38-44 and 48-49, are not elastomeric hydrogels, but thermoplastic polymers, which may have

very different physical and chemical properties. Thus, one of skill in the art at the time of the invention would not have expected that the methods used in Bawa would work with these materials. Specifically, unlike crosslinked elastomers, thermoplastic polymers can flow upon heating or application of densified carbon dioxide and then solidify into a rigid polymer upon cooling or depressurization, respectively (DeSimone Declaration at para. 9). In addition, upon solidification, the polymers will not necessarily return to their original form but instead may remain in their melted or deformed state. Thus, one of skill in the art at the time of the invention would not have assumed that a preformed stent could be submitted to the processes of Bawa and remain undeformed.

In passing, Bawa does state that its methods may be performed with any contact lens material and lists poly(methyl methacrylate) or PMMA, a thermoplastic polymer which is commonly used as a material for "hard" contact lenses, as one of the contact lens materials. However, as Dr. DeSimone indicates in the DeSimone Declaration, one of skill in the art at the time of the invention would have known that thermoplastic polymers would behave very differently in densified carbon dioxide and so would not necessarily be able to be used in the processes of Bawa (*see,* paras. 5-10). One of skill in the art would certainly not have assumed that a preformed stent including thermoplastic polymer material would maintain its structure while being subjected to the methods recited in Claims 27-34, 38-44 and 48-49. Therefore, the skilled artisan would have had no reasonable expectation of success *a priori* for performing Bawa's methods with stents including thermoplastic polymeric material.

Furthermore, Applicants submit that the skilled artisan would also have not been motivated to use any of the specific polymers recited in Claims 27-34, 38-44 and 48-49 because, as the instant specification (page 8, line 29 – page 9, line 27) describes, all of the recited polymers are erodible. One of skill in the art would not use an erodible polymer as a contact lens material because it would undesirably erode while in the eye. Bawa also teaches away from the use of erodible polymers by stating that its hydrogels are "hydolytically stable" and "biologically inert." (Bawa, col. 6, lines 6-8). Therefore, one of skill in the art at the time of the invention would

not have been motivated to modify the teaching of Bawa to reach the methods recited in Claims 27-34, 38-44 and 48-49.

In summary, one of ordinary skill in the art at the time of invention would have been aware of the distinctive physical and chemical characteristics of the recited thermoplastic polymers on one hand and the crosslinked elastomers that are the focus of Bawa on the other. Thus, in view of these known physical and chemical differences, one of ordinary skill in the art would have expected that the claimed polymers and the materials described by Bawa would exhibit different properties, and would therefore respond differently to treatment with densified carbon dioxide. Thus, there would have been no reasonable expectation of success *a priori* by the ordinarily skilled worker in carrying out the claimed methods without deforming the treated stent. In addition, the skilled artisan would not be motivated to try Bawa's methods with the recited polymers because they are erodible, and therefore, not suitable as contact lens material.

In view of the foregoing, Applicants respectfully submit that Bawa does not disclose or suggest the presently claimed invention, and request that the rejections on this basis be withdrawn.

§103(a) Rejection over Hile in view of Cook is Overcome

Claims 27-49 further stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hile in view of Cook. Applicants respectfully disagree with this rejection. Nonetheless, Claims 35-37 and 45-47 are herein canceled without prejudice, thus mooting the rejection as it applies to these claims. Regarding pending Claims 27-34, 38-44 and 48-49, this rejection is respectfully traversed below.

As an initial point, Hile is directed to techniques for preparing polymer foams containing encapsulated proteins using supercritical carbon dioxide. As such, Hile does not teach or suggest treating stents with carbon dioxide. In Hile, the polymeric material is subjected to carbon dioxide while it is dissolved in an organic liquid, not as a stent or a solid form of any kind. Furthermore, the foams produced by Hile's methods, with or without protein therein, would be unsuitable for use as stents.

In addition, as described in the DeSimone Declaration, although Hile refers to the extraction of solvents from polymers, the processes of Hile are fundamentally different than those described in Claims 27-34, 38-44 and 48-49 (para. 12). In the processes of Hile, a water-in-solvent emulsion is first prepared, such that a protein is dissolved in the aqueous phase and a polymer is dissolved in the organic phase. The emulsion is then pipetted into a mold to be placed in a high pressure reaction cell. The high pressure reaction cell is then pressurized with carbon dioxide until supercritical conditions are achieved (31°C and 1070 psi) and extraction occurs as the solvent associated with the polymer dissolves in the carbon dioxide. At some point, the cell is rapidly depressurized, which causes the polymer to foam and the carbon dioxide, and any solvent dissolved in it, to be evacuated from the cell. Hile describes the evacuation of the solvent upon depressurization and foaming as the "extraction."

In contrast to the processes described in Hile, the instant claims are directed toward the extraction of solvent from a structurally defined solid stent. As the stent is introduced to the carbon dioxide in a form that is desirable for intraluminal use, plasticization and flow of the stent is undesirable because it can deform the structure of the stent. Thus, the processes of Hile are different than the processes of Claims 27-34, 38-44 and 48-49 for at least the reasons that in the present claims, 1) a defined structure is formed before application of carbon dioxide, in contrast to the

formation of the foamed structure after the application of carbon dioxide in Hile; and 2) the solvent or other residue is removed from a solid polymer, in contrast to the methods of Hile, in which solvent is removed from a dissolved polymer. Clearly, one of skill in the art at the time of the invention would not have been motivated to use a method of producing foams from dissolved polymeric material, which incidentally also partially removes the solvent which dissolved the polymer, for extracting toxic materials from a solid stent.

Further, the deficiencies of Hile are not remedied by combination with Cook. Cook merely discloses that PLGA is known for coating stents. However, what Hile and Cook fail to disclose or suggest, either alone or in combination, is the treatment of a biocompatible stent comprising the recited polymers by immersing the stent in a densified carbon dioxide composition such that toxic materials are absorbed by the densified carbon dioxide composition.

In view of the foregoing, it is respectfully submitted that Hile and Cook, taken alone or in combination, fail to disclose or suggest the present invention to one of ordinary skill in the art at the time of invention. Accordingly, it is respectfully requested that the outstanding rejection under 35 U.S.C.§103(a) over these references be withdrawn.

New Claims 50-56

For the reasons described above with reference to Claims 27-34, 38-44 and 48-49, Applicants also submit that new Claims 50-56 are patentable over Bawa, and also over Hile in view of Cook. Therefore, Applicants respectfully request that Claims 50-56 be passed to allowance.

In view of the above, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

Needham James Boddie, II
Registration No. 40,519

Attachments:
DeSimone Declaration
Clean copy of amended claims

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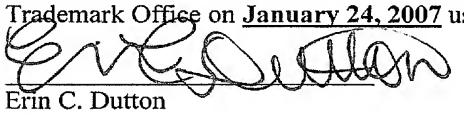

Erin C. Dutton